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13. ABSTRACT *(Maximum 200 Words)*

This is a randomized, double blind controlled study designed to assess the effects of electroacupuncture (EA) on nausea and vomiting induced by chemotherapy in cancer patients. The primary aim of this study is to evaluate the usefulness of EA as an adjuvant on N/V in chemotherapy patients who do not respond to conventional antiemetics. Seventy-five outpatients will be recruited from the University of Maryland Baltimore (UMB) Cancer Center who have shown refractory to 5-HT_3 antiemetic and randomized into three treatment groups (n=25 per group): (1) EA: 10 hz, 10 min, (2) EA: 100 Hz, 10 min, and (3) a sham acupuncture control group. Research team personnel are in place and recruitment began in January 2000. As of August 31, 2001, 101 patients had been screened, 18 judged as eligible, and 10 have consented to go on the protocol and have now completed the study. The study has experienced difficulty with obtaining sufficient numbers of patients due to the low prevalence of nausea and vomiting among the chemotherapy patients at the UMB Cancer Center. For this reason an amendment is being submitted to the IBB (and permission will be requested from the DOD) to extend the study into the Cancer Center's Bone Transplant Unit, which (pending approval) will begin in November, 2001.

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INTRODUCTION

Nausea and vomiting (N/V) are significant side effects of cancer chemotherapy which can both affect a patient's quality of life and compromise a physician's ability to deliver adequate doses of effective chemotherapy. The purposes of this study are: 1) to evaluate the effectiveness of EA as an adjunctive therapy for minimizing nausea and vomiting caused by chemotherapy; 2) to compare the effectiveness of two protocols of EA on N/V; and 3) to measure the usefulness of EA in improving the general quality of life of cancer patients. This is a randomized, double blind controlled clinical trial with independent assessment of the effect of Electroacupuncture (EA) on nausea and vomiting induced by chemotherapy in patients who do not respond to 5-HT_3 antiemetics. The specific aims of this study are three-fold: 1) to evaluate the usefulness of EA as an adjuvant on N/V in chemotherapy patients who do not respond to 5-HT_3 antiemetics; 2) to compare the effectiveness of two protocols of EA on N/V; and 3) to document the benefit of EA on improving the general quality of life of cancer patients. Seventy five outpatients recruited from Cancer Center, UMB, who have shown refractory to 5-HT_3 antiemetic, will be randomized into three treatment groups (n=25 per group): treatment group I (EA: 10 Hz, 10 min), treatment group II (EA: 100 Hz, 10 min), and sham control group.

BODY

During the first 3 months of the study, the research personnel were hired, including research nurses and acupuncturists. Several research team meetings with the PI and co-investigators, physicians and nurses in the Cancer Center, the research coordinator, and the biostatistician have been held. Patient recruitment began in January 2000. As of August 31, 2001 there have been 101 patients screened for the study. Of the 101 screened, 18 patients were eligible. Ten of the 18 eligible patients have consented to go on protocol and have completed the study. Of the eight eligible patients who chose not to participate, one lived at too great of a distance and was unwilling to travel to the University for the additional appointments necessary for the study, one reported that she was soon to have additional surgery and did not wish to participate, and 10 gave no specific reason for not participating other than they were not interested. Complete data have been obtained from the 10 participating patients and the procedures appear to be working quite well, although due to the low enrollment (ten subjects total) no analyses have been performed to date. No subjects have withdrawn and no serious adverse events due to acupuncture treatment have been observed.

The study continues to experience difficulty with obtaining sufficient recruitment. An amendment requesting Institutional Review Board (IRB) permission to expand the eligibility criteria to include chemotherapy patients who are suffering from cancer other than breast cancer was approved by the UM IRB and the Department of Defense, but unfortunately this did not solve the problem. We have consequently received permission to use patients within the University of Maryland Bone Marrow Transplant Center and are currently pursuing IRB permission to include these patients. When this is obtained, we will request permission from the Department of Defense to change the protocol slightly to incorporate this change, since this center is an inpatient facility involving extremely aggressive chemotherapy and a sufficiently large patient population to allow us to finish the study.

KEY RESEARCH ACCOMPLISHMENTS

- Study research personnel have been hired
- Patient recruitment has begun
- Permission to recruit patients in the UMB Bone Marrow Transplant Center has been obtained and a protocol amendment has been submitted to the UMB IRB.

REPORTABLE OUTCOMES

NA

CONCLUSIONS:

This is an on-going study to investigate the effect of Electroacupuncture (EA) on nausea and vomiting induced by chemotherapy in the cancer patients who do not respond to conventional antiemetics. Research team personnel have been hired. Patient recruitment began in January 2000. However, the patient enrollment has been unexpected slow. This is partially due to relatively small breast cancer patient pool at the UMB Cancer Center. An amendment requesting IRB permission to expand the eligibility criteria to include chemotherapy inpatients in the UMB Bone Marrow Transplant Center has been submitted. The expanded recruitment procedure will begin in Nov. 2000. It is hoped that by expanding the pool of participants the study will have a sufficient number of participants to complete the project.

REFERENCES: NA

APPENDICES : NA